K013072

NOV 2 6 2002

510(k) Summary

SPONSOR:	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700 Contact: Thomas M. Maguire
DEVICE NAME:	chronOS
CLASSIFICATION:	chronOS: Unclassified. Product Code is MQV. Perfusion Syringe: Piston Syringe; Product Code is FMF.
PREDICATE DEVICE:	Pro Osteon 500R Resorbable Bone Void Filler Vitoss Scaffold Synthetic Bone Void filler
DEVICE DESCRIPTION:	Synthes chronOS is a porous, osteoconductive, resorbable bone void filler made from ß-Tricalcium Phosphate (TCP). chronOS features a uniform three dimensional pore structure. Pore diameters within the material range from 100 to 500 µm. chronOS is provided sterile in granules and preformed shapes (e.g. blocks, cylinders, wedges). chronOS may be packaged with a perfusion syringe that is used to mix the bone void filler with the patient's blood components.
INTENDED USE:	Synthes chronOS is intended for use as a bone void filler in voids or gaps that are not intrinsic to the stability of the bony structure. chronOS is indicated for use in the treatment of bony defects created surgically or through traumatic injury. chronOS is indicated to be gently packed or placed into bony voids or gaps of the skeletal system (i.e. the extremities, spine, and pelvis). Following placement in the bony void or gap, the calcium phosphate scaffold resorbs and is replaced with bone during the healing process.
MATERIAL:	ß-Tricalcium Phosphate $[Ca_3(PO_4)_2]$

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 26 2002

Mr. Thomas M. Maguire
Regulatory Compliance Manager
Synthes (USA)
1690 Russell Road
Post Office Box 1766
Paoli, PA 19301

Re: K013072
Synthes chronOS Tricalcium Phosphate and Synthes Perfusion Syringe
Regulatory Class: unclassified
Product code: MQV
Dated: August 29, 2002
Received: August 30, 2002

Dear Mr. Maguire:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES

2.0 Indications for Use Statement

510(k) Number (if known): K013072

Device Name: Synthes (USA) ChronOS

Indications/Contraindications:

Synthes ChronOS is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. ChronOS is indicated for use in the treatment of bony defects created surgically or through traumatic injury.

ChronOS Tricalcium Phosphate is indicated to be gently packed or placed into bony voids or gaps of the skeletal system (i.e. the extremities, spine, and pelvis). Following placement in the bony void or gap, the calcium phosphate scaffold resorbs and is replaced with bone during the healing process.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013072